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FOR PRESENTATION BEFORE THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS
LEGISLATIVE HEARING
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Chairman Coffman, Ranking Member Kirkpatrick, Distinguished Members of the House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations:

Thank you for the opportunity to come before you today in support of the "Biological Implant Tracking and Veteran Safety Act of 2014." This critical legislation directs the Secretary of Veterans Affairs to adopt a standard identification protocol for use in the procurement of biological implants by the Department of Veterans Affairs. By building upon the past success of the implementation of the Unique Device Identifier or UDI, this legislation will ensure that biological implants used within the Department can be appropriately tracked from the donor of the human tissue all the way to the recipient. This critical capability for "track and trace" efforts will enhance patient safety, expedite product recalls when necessary, and assist with inventory management.

This legislation takes a bold step to expand the application of the concept of the UDI to all tissue products, including those tissue-devices (which are already covered by the UDI), as well as another product category: certain biological implants or, as termed by the Food and Drug Administration (FDA), 361 human cells, tissues, and cellular and tissue-based products or HCT/Ps. While many of the biological implants do have company specific bar coding information, by requiring a standardized format for those bar codes, as outlined in this legislation, it is easier for the Department of Veterans Affairs medical facilities to utilize universal bar coding conventions and to realize the full benefit of a unique identification system. Finally, by applying a system which has been developed for devices to biological implants, such a solution should also be applicable to other health care settings and other health care systems (such as the Department of Defense health care system or the private sector).

As the Secretary of Veterans Affairs opts to adopt the standard identification protocol for tissues (both devices and non-devices), I urge you to ensure that the Secretary provide a menu of options for such adoption. Under the UDI final rule, FDA has done just that be providing for multiple entities called issuing agencies. At this time, FDA has provided for three different issuing agencies: (1) GS1, (2) Health Industry Business Communications Council (HIBCC), and (3) ICCBBA. I hope that this flexibility is maintained within the Department of Veterans Affairs. However, given that the bill language already suggests that the unique identification system is comparable to what the UDI provides, we believe the intent to provide that flexibility is inherent in the legislation.

For those of you unfamiliar with my organization, the American Association of Tissue Banks (AATB) is a professional, non-profit, scientific and educational organization. It is the only national tissue banking organization in the United States, and its membership totals **more than 125 accredited tissue banks and approximately 850 individual members**. These banks recover tissue from more than **30,000 donors** and distribute in excess of **two million allografts for more than one million tissue transplants performed annually in the U.S**. The vast majority of tissue banks that process tissue maintain AATB accreditation,

and the AATB estimates that only 5-10% of the allografts distributed are from tissue donors who were not determined to be suitable by the medical director of an AATB-accredited tissue bank. The AATB does not have a similar estimation for tissue distributed by tissue distribution intermediaries.

The Association was founded in 1976 by a group of doctors and scientists who had started in 1949 our nation's first tissue bank, the United States Navy Tissue Bank. Recognizing the increasing use of human tissue for transplant, these individuals saw the need for a national organization to develop standards, promote ethics and increase donations.

Since its beginning, the AATB has been dedicated to improving and saving lives by promoting the safety, quality and availability of donated human tissue. To fulfill that mission, the **AATB publishes standards and guidance documents, accredits tissue banks, and** certifies personnel. The Association also interacts with regulatory agencies and health authorities, and conducts educational meetings.

First published in 1984 and presently in its 13th edition, the AATB's *Standards for Tissue Banking* are recognized in both the United States and around the world as the **definitive guide for tissue banking**. These Standards are the only private tissue-banking standards published in the United States, and they are the most comprehensive and detailed tissue-banking standards in the world. As such, the **AATB's Standards have served as the model for federal and state regulations as well as several international directives and standards.** Currently, the statutes and/or regulations of 19 states (i.e., California, Connecticut, District of Columbia, Florida, Georgia, Idaho, Illinois, Kentucky, Maryland, Montana, New Jersey, North Carolina, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Virginia, and Wisconsin) reference AATB's Standards, institutional accreditation, or individual certification. And, these Standards are the basis of our accreditation process.

Human tissue is used in a wide variety of medical procedures in the VHA facilities, ranging from wound care management to hernia repair to orthopedic procedures, among many others. Human tissue is also used in a wide array of dental services, such as bone augmentation and gum tissue grafting procedures. In fact, according to a report for this committee, biologics accounted for approximately $75 million in VHA acquisitions in fiscal year 2013. Recently, human tissue "track and trace" concerns have been raised with the VHA, both at the agency and Congressional level. A recent report by the Government Accountability Office (GAO), prepared for this Committee, noted that one Veterans Affairs Medical Center (VAMC) had a high percentage of purchases missing serial numbers or lot numbers (16 percent in the first three quarters of fiscal year 2013).[1] I'm hopeful that this legislation will appropriately address this outstanding concern, without providing an undue burden on the health care system. For this and many other reasons, I am here in support of this critical legislation.

However, I would be remiss if I didn't mention one aspect of the legislation which is disappointing: The current legislation lacks a requirement that biological implants purchased by the VHA be procured from accredited tissue banks and accredited tissue distribution intermediaries. While I understand that some of you may be concerned about imposing such a requirement because we are a private entity, I would just note that there are other instances in which the VHA has decided that private accreditation is not only appropriate but required. Specifically, the VHA requires medical facilities to receive and retain accreditation by the Joint Commission, a private accrediting agency. Leading medical centers of excellence require AATB accreditation of vendors from whom they procure tissue grafts. In addition, the American Academy of Orthopaedic Surgeons (AAOS) recommends the use of tissue from banks that are

[1] http://www.gao.gov/assets/670/660105.pdf

accredited by the AATB.[2] By not requiring that FSS contractors adhere to the highest safety standards required by the AATB's accreditation process, I remain concerned about the overall safety and quality of the products provided to our veterans.

I welcome your questions.

I yield back my time.

[2]http://www.aaos.org/about/papers/advistmt/1011.asp